IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMACYCLICS LLC and JANSSEN BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 18-192 (CFC)
	)	CONSOLIDATED
FRESENIUS KABI USA, LLC, et al.,	)	
Defendants.	)	

PLAINTIFFS' ANSWER TO DEFENDANT CIPLA LIMITED'S FIRST AMENDED COUNTERCLAIMS

Plaintiffs/Counterclaim Defendants Pharmacyclics LLC ("Pharmacyclics") and Janssen Biotech, Inc. ("Janssen"), (collectively, "Plaintiffs"), by their undersigned attorneys, hereby answer Defendant/Counterclaim Plaintiff Cipla Limited's Counterclaims to Plaintiffs' First Amended Complaint ("First Amended Counterclaims"), filed on March 1, 2019 (D.I. 113), as follows:

CIPLA LIMITED AND CIPLA USA INC.'S ANSWER AND AFFIRMATIVE DEFENSES

Paragraphs 1–134 and the "Affirmative Defenses" of the Answer, Defenses, and Counterclaims to Plaintiffs' First Amended Complaint (D.I. 113) filed by Cipla Limited and Cipla USA Inc. (collectively, "the Cipla Defendants") are not part of the First Amended Counterclaims and require no response by Plaintiffs.

ANSWER TO CIPLA LIMITED'S FIRST AMENDED COUNTERCLAIMS

Plaintiffs deny all allegations in Cipla Limited's First Amended Counterclaims except as expressly admitted below.

THE PARTIES

1. Counterclaim Plaintiff Cipla [Limited] is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400 013, India.

ANSWER: Upon information and belief, admitted.

2. On information and belief and as Counterclaim Defendants allege in their First Amended Complaint, Counterclaim Defendant Pharmacyclics LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 999 East Arques Avenue, Sunnyvale, California 94085.

ANSWER: Admitted.

3. On information and belief, Pharmacyclics LLC was formerly known as Pharmacyclics Inc.

ANSWER: Plaintiffs admit that, in connection with the acquisition of Pharmacyclics Inc. by AbbVie Inc. in 2015, ownership of all shares of Pharmacyclics Inc. was transferred to Pharmacyclics LLC. Plaintiffs deny the remaining allegations of Paragraph 3.

4. On information and belief and as Counterclaim Defendants allege in their First Amended Complaint, Counterclaim Defendant Janssen Biotech, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044.

ANSWER: Plaintiffs admit that Plaintiff Janssen Biotech, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044. Plaintiffs deny the remaining allegations of Paragraph 4.

JURISDICTION AND VENUE

5. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337, 1338(a), 2201 and 2202. Counterclaim Defendants did not contest subject matter jurisdiction in their Answer to Cipla Limited's Counterclaims. (18-cv-00247-CFC, D.I. 19).

ANSWER: Paragraph 5 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that Cipla Limited purports to assert declaratory judgment counterclaims. Plaintiffs also admit that they did not contest subject matter jurisdiction, for purposes of this action only, in their Answer to Cipla Limited's Counterclaims to Plaintiffs' Complaint. *See* C.A. No. 18-247-CFC, D.I. 19, Answer to ¶ 5. Plaintiffs further admit that for purposes of this action only, Plaintiffs do not contest that this Court has subject matter jurisdiction with respect to Cipla Limited's First Amended Counterclaims (D.I. 113). Plaintiffs deny the remaining allegations of Paragraph 5, and further deny that Cipla Limited's First Amended Counterclaims have any merit.

6. The Court has personal jurisdiction over Counterclaim Defendants because, *inter alia*, Counterclaim Defendants initiated and are prosecuting this action in this judicial district, and because, on information and belief, they regularly transact business in and derive substantial revenue from Delaware, either directly or through agents, sell products in Delaware, including the IMBRUVICA® product that is the subject of this case, and have purposefully availed themselves of this forum. Counterclaim Defendants did not contest personal jurisdiction in their Answer to Cipla Limited's Counterclaims. (18-cv-00247-CFC, D.I. 19).

ANSWER: Paragraph 6 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that they have sued the Cipla Defendants in this judicial district in the present action. Plaintiffs further admit that they manufacture and/or market IMBRUVICA® for sale throughout the United States, including in this judicial district. Plaintiffs further admit that, for the purposes of this action only, Plaintiffs did not contest personal jurisdiction in this judicial district with respect to Cipla Limited's First Amended Counterclaims. *See* C.A. No. 18-247-CFC, D.I. 19, Answer to ¶ 6. Plaintiffs further admit that for the purposes of this action only, they do not contest that this Court has personal jurisdiction with respect to Cipla Limited's Counterclaims to Plaintiffs' First Amended Complaint (D.I. 113). Plaintiffs deny the remaining allegations of Paragraph 6.

7. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

ANSWER: Paragraph 7 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that they have sued the Cipla Defendants in this judicial district in the present action. For the purposes of this action only, Plaintiffs do not contest venue in this judicial district with respect to Cipla Limited's First Amended Counterclaims (D.I. 113). Plaintiffs deny the remaining allegations of Paragraph 7.

8. Venue is proper because Counterclaim Defendants consented to the propriety of venue in this Judicial District by filing their claim in this Judicial District, in response to which these Counterclaims are asserted. Counterclaim Defendants did not contest venue in their Answer to Cipla Limited's Counterclaims. (18-cv-00247-CFC, D.I. 19).

ANSWER: Paragraph 8 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that they have sued the Cipla Defendants in this judicial district in the present action. Plaintiffs further admit that for the purposes of this action only, Plaintiffs did not contest venue in this judicial district with respect to Cipla Limited's Counterclaims to Plaintiffs' Complaint. *See* C.A. No. 18-247-CFC, D.I. 19, Answer to ¶ 7. Plaintiffs further admit that for the purposes of this action only, they do not contest venue in this judicial district with respect to Cipla Limited's First Amended Counterclaims. Plaintiffs deny the remaining allegations of Paragraph 8.

BACKGROUND

9. According to the United States Food & Drug Administration ("FDA") publication titled Approved Drug Products and Therapeutic Equivalence Evaluations (the "Orange Book"), Counterclaim Defendant Pharmacyclics holds approved New Drug Application ("NDA") No. 205552 for IMBRUVICA®.

ANSWER: Plaintiffs admit that Pharmacyclics holds approved New Drug Application ("NDA") No. 205552 for IMBRUVICA®. Plaintiffs deny the remaining allegations of Paragraph 9.

10. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

ANSWER: Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs refer to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, for the terms thereof, and deny the remaining allegations of Paragraph 10.

11. U.S. Patent No. 9,296,753 ("the '753 Patent"), on its face, is titled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," and states that it was issued on March 29, 2016.

ANSWER: Admitted.

12. U.S. Patent No. 9,725,455 ("the '455 Patent"), on its face, is titled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," and states that it was issued on August 8, 2017.

ANSWER: Admitted.

13. U.S. Patent No. 9,540,382 ("the '382 Patent"), on its face, is titled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," and states that it was issued on January 10, 2017.

ANSWER: Admitted.

14. U.S. Patent No. 9,713,617 ("the '617 Patent"), on its face, is titled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," and states that it was issued on July 25, 2017.

ANSWER: Admitted.

15. U.S. Patent No. 8,754,090 ("the '090 Patent"), on its face, is titled "Use of Inhibitors of Bruton's Tyrosine Kinas [sic] (BTK)," and states that it was issued on June 17, 2014.

ANSWER: Plaintiffs admit that the '090 Patent, on its face, is titled "Use of Inhibitors of Bruton's Tyrosine Kinase (BTK)," and states that it was issued on June 17, 2014.

16. U.S. Patent No. 9,125,889 ("the '889 Patent"), on its face, is titled "Use of Inhibitors of Bruton's Tyrosine Kinase (BTK)," and states that it was issued on September 8, 2015.

ANSWER: Admitted.

17. U.S. Patent No. 10,106,548 ("the '548 Patent"), on its face, is titled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," and states that it was issued on October 23, 2018.

ANSWER: Admitted.

18. U.S. Patent No. 10,125,140 ("the '140 Patent"), on its face, is titled "Crystalline Forms of a Bruton's Tyrosine Kinase Inhibitor," and states that it was issued on November 13, 2018.

ANSWER: Admitted.

19. Counterclaim Defendant Pharmacyclics is listed on the face of the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '548 Patent, and the '140 Patent as the assignee of said patents.

ANSWER: Admitted.

20. Pharmacyclics, Inc. is listed on the face of the '090 Patent and the '889 Patent as the assignee of said patents.

ANSWER: Plaintiffs admit that Plaintiff/Counterclaim Defendant Pharmacyclics is the assignee and owner of the '090 Patent and the '889 Patent. Plaintiffs deny the remaining allegations of Paragraph 20.

21. On information and belief Pharmacyclics owns the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, the '889 Patent, the '548 Patent, and the '140 Patent.

ANSWER: Admitted.

22. On information and belief and as Counterclaim Defendants allege in their First Amended Complaint, Counterclaim Defendant Janssen holds an exclusive license to the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, the '889 Patent, the '548 Patent, and the '140 Patent.

ANSWER: Admitted.

23. On information and belief, Counterclaim Defendant Pharmacyclics caused the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, the '889 Patent, the '548 Patent, and the '140 Patent to be listed in the Orange Book as patents that cover IMBRUVICA® or methods of using IMBRUVICA®.

ANSWER: Plaintiffs admit that the '753, '455, '382, '617, '090, '889, '548, and '140 Patents are listed in the Orange Book in connection with NDA No. 205552 for IMBRUVICA®. Plaintiffs deny the remaining allegations of Paragraph 23.

24. On February 12, 2018, Counterclaim Defendants filed this lawsuit alleging infringement of the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, and the '889 Patent.

ANSWER: Admitted.

25. Cipla Limited submitted ANDA No. 211249 (the "Cipla ANDA") to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, or sale in the United States of a generic Ibrutinib Capsule, 140 mg drug product (the "Cipla ANDA Product"). The Cipla ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal, Food, Drug and Cosmetic Act ("FDCA") that the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, and the '889 Patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Cipla ANDA Product.

ANSWER: On information and belief, Plaintiffs admit that the Cipla Defendants submitted an ANDA to FDA seeking approval to engage in the commercial manufacture, use, or sale of Cipla's ANDA Product prior to the expiration of the '753, '455, '382, '617, '090, and '889 Patents, and that the ANDA was assigned No. 211249 by FDA. Further, on information and belief, Plaintiffs admit that Cipla submitted a purported certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") of the FDCA for, *inter alia*, the '753, '455, '382, '617, '090, and '889 Patents. Plaintiffs deny the remaining allegations of Paragraph 25.

26. On December 29, 2017, Cipla Limited sent a letter to, *inter alia*, Pharmacyclics pursuant to 21 U.S.C. § 355(j)(2)(B), providing notification that Cipla Limited submitted its ANDA No 211249 to FDA, and that the ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the FDCA that the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, and the '889 Patent are invalid, unenforceable, and/or not infringed by Cipla's ANDA Product.

ANSWER: On information and belief, Plaintiffs admit that Pharmacyclics received a letter, dated December 29, 2017, sent on behalf of Cipla Limited ("Notice Letter"), stating that Cipla Limited submitted an ANDA to FDA seeking approval to engage in the commercial

manufacture, use, or sale of Cipla's ANDA Product prior to the expiration of the '753, '455, '382, '617, '090, and '889 Patents, and that the ANDA was assigned No. 211249 by FDA. Plaintiffs further admit that the Notice Letter represented that Cipla Limited submitted a purported Paragraph IV certification for, *inter alia*, the '753, '455, '382, '617, '090, and '889 Patents in connection with ANDA No. 211249. Plaintiffs deny the remaining allegations of Paragraph 26.

27. The Notice Letter is incorporated by reference, including its detailed descriptions of the facts and circumstances sufficient to show that the claims of the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, and the '889 Patent are invalid and/or not infringed.

ANSWER: Denied.

28. The Notice Letter contained an offer of confidential access to relevant portions of ANDA No. 211249 that Counterclaim Defendants could use to determine whether the Cipla ANDA Product would infringe any valid claim of the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, and the '889 Patent.

ANSWER: Plaintiffs admit that the Notice Letter purported to contain an Offer of Confidential Access to certain information from ANDA No. 211249. However, Cipla Limited's purported Offer of Confidential Access contained in its Notice Letter did not comply with 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an Offer of Confidential Access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information," at least because it contained unreasonable restrictions on who could view the Cipla ANDA, well beyond those that would apply under a protective order. Plaintiffs admit that Cipla Limited's purported Offer of Confidential Access did not permit any of Pharmacyclics' in-house attorneys to access ANDA No. 211249, nor did it permit any scientific experts to access ANDA No. 211249, nor did it permit any access to ANDA No. 211249 for Plaintiff Janssen. Additionally, Plaintiffs admit that

Cipla Limited's purported Offer of Confidential Access contained provisions that unreasonably restricted the ability of counsel receiving access to ANDA No. 211249 to engage in any patent prosecution or work before or involving the FDA. Plaintiffs deny the remaining allegations of Paragraph 28.

29. Upon information and belief, and as Counterclaim Defendants allege in their First Amended Complaint, Pharmacyclics received the Notice Letter.

ANSWER: Admitted.

30. On February 1, 2019, the parties filed a stipulation allowing Counterclaim Defendants to file an Amended Complaint (18-cv-192, D.I. 86), which added allegations against Cipla for the infringement of the '548 and '140 Patents. On February 5, 2019, the Court approved the stipulation and Counterclaim Defendants filed a First Amended Complaint Against Cipla for Patent Infringement adding allegations against Cipla for infringement of the '548 and '140 Patents.

ANSWER: Plaintiffs admit that on February 1, 2019, Plaintiffs and the Cipla Defendants filed a stipulation allowing Plaintiffs to file a First Amended Complaint against the Cipla Defendants. *See* C.A. No. 18-192-CFC, D.I. 86. Plaintiffs further admit that on February 5, 2019, the Court entered the stipulation and Plaintiffs' First Amended Complaint against the Cipla Defendants, which included, *inter alia*, claims that the Cipla Defendants infringed the '548 and '140 Patents under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification; and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States, of the Cipla ANDA Product would actively infringe, induce the infringement of, and/or contribute to the infringement of the '548 and '140 Patents in violation of 35 U.S.C. §§ 271(a), (b), and/or (c) *See id.*, D.I. 90, 91. Plaintiffs deny the remaining allegations of Paragraph 30.

31. A justiciable controversy exists as to the infringement and validity of the '753 Patent, the '455 Patent, the '382 Patent, the '617 Patent, the '090 Patent, the '889 Patent, the '548 Patent, and the '140 Patent because Counterclaim Defendants brought an action alleging that the importation, manufacture, use, offer for sale, or sale of the products that are the subject of the Cipla ANDA would infringe those patents, and Cipla has denied the alleged infringement

and further alleges that the claims of the ’753 Patent, the ’455 Patent, the ’382 Patent, the ’617 Patent, the ’090 Patent, the ’889 Patent, the ’548 Patent, and the ’140 Patent are invalid. This controversy is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

ANSWER: Paragraph 31 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the ’753, ’455, ’382, ’617, ’090, ’889, ’548, and ’140 Patents under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification; and that the Cipla Defendants’ manufacture, use, sale, offer for sale, or importation into the United States, of the Cipla ANDA Product would actively infringe, induce the infringement of, and/or contribute to the infringement of the ’753, ’455, ’382, ’617, ’090, ’889, ’548, and ’140 Patents in violation of 35 U.S.C. §§ 271(a), (b), and/or (c). Plaintiffs deny the remaining allegations of Paragraph 31.

COUNT I
DECLARATORY JUDGMENT OF INVALIDITY OF THE ’753 PATENT

32. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–31 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 31 above, and each paragraph of their Complaint, as if fully set forth herein.

33. Each and every claim of the ’753 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

34. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla’s ANDA Product in the United States, or importation of Cipla’s ANDA Product into the United States, will infringe any valid and enforceable claim of the ’753 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 34 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '753 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '753 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 34.

35. Cipla is entitled to a declaratory judgment that each and every claim of the '753 Patent is invalid.

ANSWER: Denied.

COUNT II
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '753 PATENT

36. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–35 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 35 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

37. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '753 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

38. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '753 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

39. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '753 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 39 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '753 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '753 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 39.

40. Cipla is entitled to a declaratory judgment that the '753 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '753 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT III
DECLARATORY JUDGMENT OF INVALIDITY OF THE '455 PATENT

41. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–40 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 40 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

42. Each and every claim of the '455 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

43. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '455 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 43 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '455 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '455 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 43.

44. Cipla is entitled to a declaratory judgment that each and every claim of the '455 Patent is invalid.

ANSWER: Denied.

COUNT IV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '455 PATENT

45. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–44 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 44 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

46. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '455 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

47. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '455 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

48. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '455 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 48 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their Complaint includes claims that the Cipla Defendants infringed the '455 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '455 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 48.

49. Cipla is entitled to a declaratory judgment that the '455 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '455 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT V
DECLARATORY JUDGMENT OF INVALIDITY OF THE '382 PATENT

50. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–49 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 49 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

51. Each and every claim of the '382 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

52. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '382 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 52 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '382 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '382 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 52.

53. Cipla is entitled to a declaratory judgment that each and every claim of the '382 Patent is invalid.

ANSWER: Denied.

COUNT VI
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '382 PATENT

54. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–53 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 53 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

55. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '382 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

56. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '382 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

57. Cipla's ANDA Product does not contain the claimed amounts of all excipients in the claims of the '382 patent or equivalents thereof.

ANSWER: Denied.

58. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '382 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 58 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '382 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '382 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 58.

59. Cipla is entitled to a declaratory judgment that the '382 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '382 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT VII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '617 PATENT

60. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–59 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 59 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

61. Each and every claim of the '617 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

62. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '617 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 62 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '617 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '617 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 62.

63. Cipla is entitled to a declaratory judgment that each and every claim of the '617 Patent is invalid.

ANSWER: Denied.

COUNT VIII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '617 PATENT

64. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–63 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 63 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

65. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '617 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

66. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '617 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

67. Cipla's ANDA Product does not contain the claimed amounts of all excipients in the claims of the '617 patent or equivalents thereof.

ANSWER: Denied.

68. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '617 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 68 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '617 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '617 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 68.

69. Cipla is entitled to a declaratory judgment that the '617 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '617 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT IX
DECLARATORY JUDGMENT OF INVALIDITY OF THE '090 PATENT

70. Cipla re-alleges and incorporates by reference the allegations in paragraphs 1–69 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 69 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

71. Each and every claim of the '090 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C.

§§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

72. The claims of the '090 Patent are invalid for obviousness-type double patenting over other patents assigned to Pharmacyclics, including but not limited to U.S. Patent No. 8,952,015 ("the '015 Patent").

ANSWER: Denied.

73. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '090 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 73 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '090 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that Cipla's manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '090 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 70.

74. Cipla is entitled to a declaratory judgment that each and every claim of the '090 Patent is invalid.

ANSWER: Denied.

COUNT X
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '090 PATENT

75. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–74 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 74 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

76. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '090 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

77. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '090 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

78. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '090 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 78 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '090 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '090 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 78.

79. Cipla is entitled to a declaratory judgment that the '090 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '090 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT XI
DECLARATORY JUDGMENT OF INVALIDITY OF THE '889 PATENT

80. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–79 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 79 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

81. Each and every claim of the ’889 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

82. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla’s ANDA Product in the United States, or importation of Cipla’s ANDA Product into the United States, will infringe any valid and enforceable claim of the ’889 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 82 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the ’889 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants’ manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the ’889 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 82.

83. Cipla is entitled to a declaratory judgment that each and every claim of the ’889 Patent is invalid.

ANSWER: Denied.

COUNT XII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’889 PATENT

84. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–83 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 83 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

85. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '889 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

86. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '889 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

87. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '889 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 87 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '889 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '889 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 87.

88. Cipla is entitled to a declaratory judgment that the '889 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '889 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT XIII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '548 PATENT

89. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–88 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 88 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

90. Each and every claim of the ’548 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

91. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla’s ANDA Product in the United States, or importation of Cipla’s ANDA Product into the United States, will infringe any valid and enforceable claim of the ’548 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 91 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the ’548 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants’ manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the ’548 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 91.

92. Cipla is entitled to a declaratory judgment that each and every claim of the ’548 Patent is invalid.

ANSWER: Denied.

COUNT XIV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’548 PATENT

93. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–92 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 92 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

94. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '548 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

95. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '548 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

96. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '548 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 96 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '548 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '548 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 96.

97. Cipla is entitled to a declaratory judgment that the '548 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '548 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT XV
DECLARATORY JUDGMENT OF INVALIDITY OF THE '140 PATENT

98. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–97 of these Counterclaims as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 97 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

99. Each and every claim of the ’140 Patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the doctrine of obviousness-type double patenting, and/or judicially-created doctrines of invalidity or unenforceability.

ANSWER: Denied.

100. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla’s ANDA Product in the United States, or importation of Cipla’s ANDA Product into the United States, will infringe any valid and enforceable claim of the ’140 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 100 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the ’140 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants’ manufacture, use, sale, offer for sale, or importation into the United States of Cipla’s ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the ’140 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 100.

101. Cipla is entitled to a declaratory judgment that each and every claim of the ’140 Patent is invalid.

ANSWER: Denied.

COUNT XVI
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’140 PATENT

102. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–101 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 101 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

103. The commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '140 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

104. The filing of Cipla's ANDA No. 211249 did not infringe any valid and enforceable claim of the '140 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

105. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, sale, or offer for sale of Cipla's ANDA Product in the United States, or importation of Cipla's ANDA Product into the United States, will infringe any valid and enforceable claim of the '140 patent either literally or under the doctrine of equivalents.

ANSWER: Paragraph 105 states a legal conclusion to which no response is required. To the extent a response is required, Plaintiffs admit that their First Amended Complaint includes claims that the Cipla Defendants infringed the '140 Patent under 35 U.S.C. § 271(e)(2)(A) by virtue of submitting ANDA No. 211249 with a Paragraph IV certification and that the Cipla Defendants' manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product would actively infringe, induce the infringement of, and/or contribute to infringement of the '140 Patent in violation of 35 U.S.C. §§ 271(a), (b), and (c). Plaintiffs deny the remaining allegations of Paragraph 105.

106. Cipla is entitled to a declaratory judgment that the '140 Patent is not infringed by Cipla and that the commercial manufacture, use, offer for sale or sale of Cipla's ANDA Product in the United States, or importation into the United States of Cipla's ANDA Product, does not and will not infringe any valid and enforceable claim of the '140 Patent either literally or under the doctrine of equivalents.

ANSWER: Denied.

COUNT XVII
EXCEPTIONAL CASE

107. Cipla re-alleges and incorporates by reference the allegations in Paragraphs 1–106 of these Counterclaims, as if fully set forth herein.

ANSWER: Plaintiffs incorporate their answers to Paragraphs 1 through 106 above, and each paragraph of their First Amended Complaint, as if fully set forth herein.

108. This case is exceptional under 35 U.S.C. § 285 and Cipla is entitled to receive its reasonable costs and attorney fees incurred in connection with this action.

ANSWER: Denied.

CIPLA LIMITED'S REQUEST FOR RELIEF

Plaintiffs deny that Cipla Limited is entitled to any of the relief it has requested or to any other relief.

AFFIRMATIVE DEFENSES

In response to Cipla Limited's First Amended Counterclaims, Plaintiffs assert the following affirmative and other defenses. In asserting these defenses, Plaintiffs do not assume the burden of proof with respect to any issue upon which applicable law puts the burden of proof upon Cipla Limited.

First Affirmative Defense

Cipla Limited's First Amended Counterclaims, in whole or in part, are barred because they fail to state a cause of action upon which relief may be granted.

Second Affirmative Defense

Cipla Limited's First Amended Counterclaims, in whole or in part, are non-justiciable and/or fail to create a case or controversy sufficient to confer subject matter jurisdiction.

Third Affirmative Defense

Plaintiffs have not knowingly or intentionally waived any applicable affirmative or other defenses and reserve the right to assert and rely upon such other affirmative and other defenses as may become available or apparent during discovery proceedings. Plaintiffs further reserve the

right to amend this Answer and/or affirmative defenses accordingly, and/or to delete affirmative defenses that Plaintiffs determine during the course of subsequent discovery are not applicable.

PLAINTIFFS' PRAYER FOR RELIEF ON CIPLA LIMITED'S FIRST AMENDED COUNTERCLAIMS

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment denying all relief sought by Cipla Limited;

B. An order dismissing Cipla Limited's First Amended Counterclaims with prejudice;

C. A judgment, order, and/or injunction granting each and every form of relief sought by Plaintiffs in their First Amended Complaint;

D. An award to Plaintiffs of their costs and expenses in this action;

E. A finding in Plaintiffs' favor that this case is exceptional, and an award of Plaintiffs' attorneys' fees pursuant to 35 U.S.C § 285;

F. An award of costs and expenses to Plaintiffs for defending against the First Amended Counterclaims; and

G. Such further and other relief as this Court deems to be just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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March 15, 2019

CERTIFICATE OF SERVICE

I hereby certify that on March 15, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on March 15, 2019, upon the following in the manner indicated:

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